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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,955	05/16/2000	WOLFGANG ROHDE	23232.0002	5703

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EXAMINER	
SORBELLO, ELEANOR	
ART UNIT	PAPER NUMBER
1633	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/462,955	Applicant(s) ROHDE ET AL.	
	Examiner Eleanor Sorbello	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-11 have been renumbered 12-22.

2. Claim 3 was amended in Amendment B which is now renumbered claim 14.

3. **Claims 11-22 are currently pending** and will be examined.

Claim Objections

4. The application is not fully in compliance the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed.

5. Claims 12-15 are objected to because of the above mentioned informalities. ie. they contain nucleotide sequences which must be identified with sequence identifiers.

6. Claim 12 is objected to because of the following informality: Acronym abbreviation for "CFDV". The term "coconut foliar decay virus" should not be abbreviated the first time it is used in the claims. Appropriate correction is required.

7. Claims 12-16, 22 lack an article, definite or indefinite, to introduce the claim. A definite or indefinite article is needed in the preamble of the claim to conform with proper grammar. Dependent claims typically refer to independent claims using the

definite article "the", while independent claims typically use the indefinite article "a" or "an."

8. Claims 11, 17-22 are objected to because they depend from misnumbered claims. It is applicants responsibility to amend the claims to recite the correct dependency. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11, 16, 17-21, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 11, 22 recites "obtained using a DNA according to claim". The metes and bounds of the claim is not clear and does not indicate how one is to use the DNA. It is suggested that the aforesaid phrase be replaced with "contain a DNA fragment according to claim".

12. Claim 16 recites the limitation "the starting fragment" in Line 3. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 16 recites the phrase "derived from". It is not clear which parts of the virus are retained and which parts are not, or in what way the "DNA fragment" is derived.

14. Claim 16 recites the following phrase: "modifying individual nucleotides or smaller groups of nucleotides". It is not clear what is meant by modifying smaller groups of

nucleotides, when the claim has already recited that modification of an individual nucleotide is within the limitation of the claim.

15. Claim 16 recites the term "comparable". It is not clear as to what the metes and bounds of this entails because the claim recites that the promoter activity is comparable to that of the starting fragment. It is not clear as to what degree of activity is required of the novel promoter.

16. Claims 17-21 provides for the use of one or more DNA fragments, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-21 are rejected **under 35 U.S.C. 101** because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a CFDV virus fragment encompassing a stem-loop structure with deletions in the translation start for the ORF-1 and ORF-2 region and has promoter activity, **does not** reasonably provide enablement for (1) a CFDV virus fragment encompassing a stem-loop structure with deletions in the ORF-1 and ORF-2 region that does not have promoter activity (2) any modification of the CFDV promoter fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a CFDV DNA fragment that has deletions in the translation start for the ORF1 and 2. The claims additionally recite that the fragment comprises repeated RPT structures, a 52 bp sequence and the TATAA sequence. Further limitations recite that the DNA fragment is modified by nucleotide substitution, deletion or insertion and still maintains promoter activity even after any of the modifications referred to are performed. The claim are also directed to chimeric constructs comprising the aforesaid promoter elements.

The specification teaches deletions in the CFDV (coconut foliar decay virus) promoter region which comprises the stem loop structure and which still maintains promoter activity. Applicants state that the crux of their invention is that the deletions in the translation start sites gave rise to enhanced activity. The CFDV fragments were then ligated into vector pRT2synGUSΔH which had been previously prepared from the plasmid pRTsynLUC. The instant invention claims that the "stem-loop" structure, is the

all important requirement for transcripion. Applicants' results demonstrate numerous constructs comprising various regions of the entire stem loop structure and deletions in the ORF 1, 2 and 3 regions, as in Table 1, page 9 of specification. The construct pRT CF4 had the highest overall promoter activity and was set at 100% for comparisons. PRT CF XS which contains the translation site for ORF1, had the least promoter activity.

The base claims read broadly on any fragment of the CFDV virus that comprises the stem-loop structure, but does not recite promoter activity. The specification does not teach one of skill in the art to make any fragment of the CFDV virus without promoter function and does not teach one of skill in the art how to use the aforesaid except for promoter function.

In view of the claims that encompass the promoter as stated above, encompassing any substitution, deletion insertion or modification of nucleotides and still maintains promoter activity the specification does not provide any guidance. The specification does not provide any guidance as to what these modifications are and why one would try to made these modifications. However if variants are possible in the case of a novel promoter, specifically what they are, and the level of expression each variant produces, has to be taught, so one of skill in the art can make and use the invention. Therefore it would require undue experimentation to determine which nucleotide substitutions in the CFDV promoter that would not alter the promoter functions. Kim et al. (1994) teach that mutations of one or more nucleotides significantly altered the strength of expression of the promoter. (see abstract). The amount of experimentation

required therefore would include trial and error determination of substitutions and/or deletions, and characterization whether or not the promoter properties of the CFDV viral promoter are retained. In view of such, the invention is not enabled over the full scope as claimed. Therefore, due to the unpredictability as explained herein applicants are not enabled for any and all variations of the CFDV promoter of the instant invention.

Therefore, the following factors when considered, does not provide for enablement. Since the CMDV promoter is a novel promoter the amount of guidance set forth as regards variants of the CMDV promoter is lacking; the breadth of the claims, which reads on any variants of the CMDV promoter; the lack of predictability of performance of the variants of the CMDV promoter and the state of the art does not enable one skilled in the art to which it pertains to make and use the invention as claimed.

In conclusion, given the nature of the invention, the state of the art, the demonstrated lack of predictability of the art, the amount of guidance set forth, the breadth of the claims, and the lack of working examples, one of skill in the art could not make and use the invention without undue experimentation.

19. Claims 12, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on any CFDV virus strain whereas the specification only refers to a fragment from one strain of CFDV as encompassed by SEQ. ID. NO: 1 and one stem loop structure. The claims additionally recite fragments according to claim 12 wherein substitutions, deletions, insertions or any modification has been conducted.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences encompassed by SEQ. ID. NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the CFDV virus fragment encompassing the following: nucleotides 211 to 911 of SEQ. ID. NO: 1, 409 to 991 of SEQ. ID. NO: 1, 611 to 991 of SEQ. ID. NO: 1 or 711 to 991 of SEQ. ID. NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 11-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,303,345. *Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 12-22 of the instant* application claim a promoter comprising fragments of a CMDV virus: nucleotide 211 to 911 of SEQ. ID. NO: 1 or 409 to 911 of SEQ. ID. NO: 1, or 611 to 911 of SEQ. ID. NO: 1 or 711 to 991 of SEQ. ID. NO: 1. Claims 1-14 of the issued patent are directed to a method of using a CFDV DNA as a promoter for expressing genes in prokaryotes or eukaryotes the method steps merely combining the aforesaid CFDV DNA fragments with an exogenous DNA forming a DNA construct. The instant application states that the promoter does not contain the ORF1 or ORF2. Even though the claims of the issued patent do not specify this limitation, the claims inherently do not comprise the ORF1 or ORF2.

Conclusion

22. Claims 11-22 are rejected.

23. The claims are free of the prior art because there is no prior teaching that would anticipate claims directed to a promoter comprising fragments of the CMDV virus without the translation sites for ORF1 and ORF2.

24. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 *(http://www.uspto.gov)* and A CLEAN COPY OF **ALL** PENDING CLAIMS IS REQUESTED to facilitate further examination.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER